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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,352

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Karl Okolotowicz

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03/29/2010

JEFFER, MANGELS, BUTLER & MARMARO, LLP
1900 AVENUE OF THE STARS, 7TH FLOOR
LOS ANGELES, CA 90067

EXAMINER

RIDER, LANCE W

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

03/29/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@jmbm.com

Office Action Summary	Application No. 10/516,352	Applicant(s) OKOLOTOWICZ, KARL	
	Examiner LANCE RIDER	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-8,10-15 and 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 and 24-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

The remarks and amendments filed on December 18th 2009 are acknowledged. Claims 1, 3-8, 10-15, and 17-23 are withdrawn, claims 2 and 16 were canceled, and claims 24-26 were added. Claims 9 and 24-26 are included in the prosecution.

Response to arguments

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

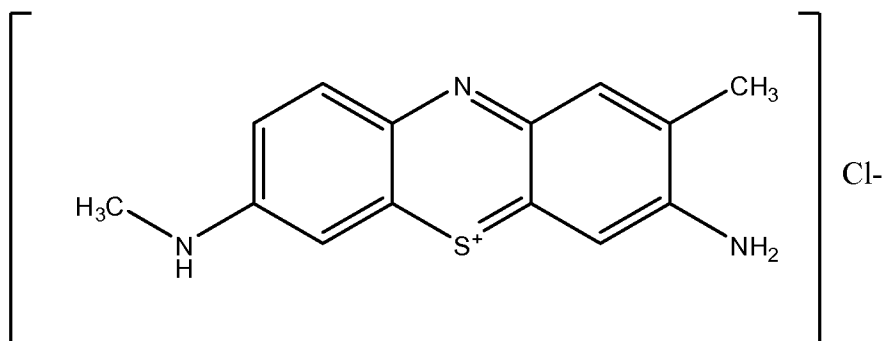
The rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Burkett, US Patent 6,086,852, in view of Cannell, R.J.P., (Natural Products Isolation, 1998) is maintained. The rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed on June 18th 2009 and for the reasons set forth below.

Rejection of claim 9 under 35 U.S.C. 103(a) as being unpatentable over Burkett, US Patent 6,086,852, in view of Cannell, R.J.P., (Natural Products Isolation, 1998).

Applicant's arguments, starting on page 14, of the reply filed on December 18th 2009 with respect to the rejections under 35 USC 103(a) have been fully considered but are not found persuasive.

Applicant argues that:

1) Burkett does not disclose or teach the following dye which is greater than 73% of the total organic dye in a composition.



In response to applicant's argument 1, Burkett teaches the exact structure of the dye shown above. (See column 2, line 30.) Burkett teaches this dye's purification using

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HPLC. (See figures 1 and 2.) Peak 6 alone is comprised of only this dye. Cannell teaches that one can collect HPLC fractions of HPLC purified compounds to yield the pure forms of those compounds. Collecting peak 6 would thus yield a composition in which the total organic dye content of the composition consists only of the above dye (peak 6 of Burkett). This meets applicant's claimed composition comprising the above dye "being greater than 73% by weight of the total organic dye content of the composition".

New Grounds of Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment filed on December 18th 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The original disclosure recites the term "N-dimethylphenylenediamine", applicant has added the new term "N-methylphenylenediamine". Applicant argues that

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the alteration is not new matter and the skilled artisan would have known that "N-dimethylphenylenediamine" really meant "N-methylphenylenediamine" as there is only one "N" recited in the specification. This is not found persuasive as the skilled artisan would have just as reasonably expected that applicant left off one "N" of "N,N-dimethylphenylenediamine", rather than unexpectedly adding a "di" to the name of a compound.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

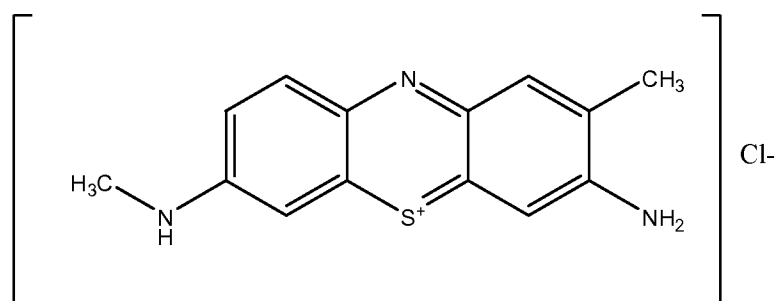
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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

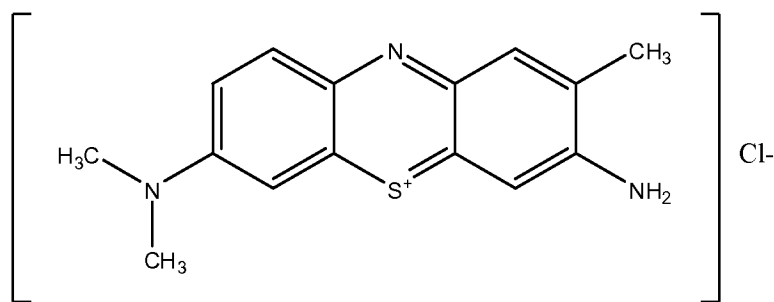
Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkett, US Patent 6,086,852, in view of Cannell, R.J.P., (Natural Products Isolation, 1998), both cited in the prior office action.

Claims 24-26 are drawn to dye compositions of the following structures alone or in combination.

I.



II.



The claims recite product-by-process limitations for how these dyes are made. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). **MPEP 2113**. Thus, in the instant claims, the applicant is only claiming the dyes, and not the methods by which they are made.

Burkett teaches compositions of dyes having the same structure of the instantly claimed dyes I and II. (See columns 2 and 3, columns 15-17, claims 1-10, and figures 1 and 2.) Burkett teaches the purification of these dyes by HPLC yielding individual peaks for each of the dyes, specifically peaks 6 (dye I) and 8 (dye II). (See figures 1 and 2.) The contents of these peaks comprise a mobile phase containing the purified dyes, meeting the limitations of at least 70 or 73% by weight of the total organic dye content of the composition being the disclosed dyes, as recited in instant claims 24-26. Burkett

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also teaches that the purification of dyes is necessary for their use in people in order to meet regulatory requirements. (See column 5, lines 15-35.)

Burkett does not teach a combination of dyes 6 and 8 in which they comprise at least 70% of the total organic dye content of a composition, or the collection of dyes 6 or 8 alone.

Cannell teaches methods for collecting fractions of HPLC samples in which, given proper separation, as is seen in figures 1 and 2 of Burkett, one can arrive at essentially pure samples of HPLC purified compounds. (See pages 199 and 200.)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to collect purified HPLC samples, such as those disclosed by Burkett using known methods of fraction collection, such as by pooling a target peak, as disclosed in Cannell, R.J.P., (Natural Products Isolation, 1998). This would allow one to obtain pure compositions of chemical compounds, such as the dyes currently claimed, which would have the met regulatory requirements taught by Burkett. The application of the method for collecting HPLC fractions taught by Cannell is simply the use of a known method used in the HPLC purification of compounds to improve a known method of purifying compounds using HPLC. The skilled artisan would have understood that the combination of dyes 6, 7, and 8 could have been collected as a single fraction from the HPLC run shown in figure 2. Collecting such a fraction containing peaks 6-8 would have formed a composition in which dyes I and II would comprise greater than 73% of the total organic dye content. The same result could have also been obtained by collecting fractions containing peaks 6 and 8 separately and mixing them together.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on M-F 11-12 and 1-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/
Examiner, Art Unit 1618

/Eric E Silverman/
Primary Examiner, Art Unit 1618